

STATE OF MICHIGAN
DEPARTMENT OF LABOR & ECONOMIC GROWTH
OFFICE OF FINANCIAL AND INSURANCE REGULATION
Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXX

Petitioner

File No. 88300-001

v

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 22nd day of April 2008
by Ken Ross
Commissioner

ORDER

I
PROCEDURAL BACKGROUND

On March 4, 2008, XXXXX (Petitioner) filed a request for external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act (PRIRA), MCL 550.1901 *et seq.* The Commissioner reviewed the material submitted and accepted the request on March 11, 2008.

Because it involved medical issues the Commissioner assigned the case to an independent review organization which provided its analysis and recommendations to the Commissioner on March 20, 2008.

II
FACTUAL BACKGROUND

The Petitioner receives health care benefits from Blue Cross Blue Shield of Michigan (BCBSM) through the Michigan Education Special Services Association (MESSA), an underwritten group. Coverage is governed by the MESSA Choices II Group Insurance for School Employees (the certificate).

The Petitioner requested preauthorization for the Pillar Palatal Implant System (the Pillar Procedure) for treatment of his moderate apnea and hypopnea. The approximate cost of this procedure is \$1,200.00. BCBSM denied preauthorization because it considers the procedure investigational for treatment of the Petitioner's condition.

The Petitioner appealed BCBSM's denial. After a managerial-level conference on January 28, 2008, BCBSM did not change its decision and issued a final adverse determination dated February 1, 2008.

III ISSUE

Did BCBSM properly deny preauthorization for the Petitioner's Pillar Procedure?

IV ANALYSIS

Petitioner's Argument

Because of his chronic sleeplessness, the Petitioner had a sleep study which diagnosed moderate apnea and hypopnea. The three treatment options discussed with doctor were an uvulopalatopharyngoplasty, which is the most invasive and the most costly; continuous passive airway pressure (CPAP), which the Petitioner tried previously and could not tolerate; and the Pillar Procedure, which involves placing three permanent implants in the soft palate.

The Petitioner found the Pillar Procedure to be the most attractive of the three because it is the least invasive, has the lowest cost, and has the shortest recovery time. It was recommended by his doctor because he thought the Petitioner was a good candidate for getting the best results from this procedure.

BCBSM has indicated that it considers the Pillar Procedure an investigation treatment, but the Petitioner argues that the FDA approved this procedure in 2004 and Wisconsin Physicians Services, the Medicare carrier in Wisconsin, Michigan, Illinois, and Indiana, covers the procedure for patients such as himself.

The Petitioner believes that the Pillar procedure offers him the best treatment for his apnea. He argues that it is not investigational and should be approved and paid for by BCBSM.

BCBSM's Argument

BCBSM believes that it is not required to cover the Petitioner's Pillar Procedure because it is investigational. The certificate, on page 51, says: "We do not pay for experimental or investigational drugs or services." The certificate defines "experimental or investigational" as "a service, procedure, treatment, device, drug, or supply that has not been scientifically demonstrated to be safe and effective for treatment of the patient's condition."

Further, BCBSM's medical policy for obstructive sleep apnea indicates that the Pillar Procedure is considered experimental/investigation treatment for this condition and not a covered benefit.

Commissioner's Review

The certificate sets forth the benefits that are covered. A procedure that is not accepted as the standard of care and has not been demonstrated to be as safe and effective as conventional or standard treatment is considered to be investigational or experimental and is not a covered benefit under the terms of the Petitioner's coverage.

The question of whether the Petitioner's proposed Pillar Procedure is considered investigational for treatment of his condition was presented to an independent review organization (IRO) for analysis as required by section 11(6) of PRIRA, MCL 550.1911(6). The IRO physician reviewer is certified by the American Board of Otolaryngology.

The IRO reviewer indicates that the Pillar Procedure has been available since it was approved by the US Food and Drug Administration (FDA) in September 2004. The IRO reviewer also noted that this procedure is one of a choice of options that is generally accepted within the field of otolaryngology. It has been accepted by the American Academy of Otolaryngology as a treatment option for obstructive sleep apnea. In the opinion of the IRO reviewer, the Pillar

Procedure is therefore not considered investigational or experimental.

The IRO reviewer also observed that traditionally, non-surgical procedures such as CPAP have been offered to patients before any consideration for surgery. However, the Petitioner tried but apparently has been intolerant of CPAP therapy, which is common in approximately 50% of people who try it. In addition, the Pillar Procedure is intended to treat mild to moderate obstructive sleep apnea documented by preoperative polysomnography. This is evident in the Petitioner's October 2, 2007, polysomnography study. The diagnostic study also documented significant oxygen saturation. The IRO reviewer concluded that the Pillar Procedure "is an appropriate choice and medically necessary to treat [the Petitioner's] mild to moderate obstructive sleep apnea syndrome."

While the Commissioner is not required in all instances to accept the IRO's recommendation, it is afforded deference by the Commissioner. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principal reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16) (b). The IRO reviewer's analysis is based on extensive expertise and professional judgment. The Commissioner can discern no reason why that judgment should be rejected in the present case.

Therefore, the Commissioner accepts the findings of the IRO that the Petitioner's proposed Pillar Procedure is not investigational and is appropriate and medically necessary for treatment of his obstructive sleep apnea.

V ORDER

Respondent BCBSM's February 1, 2008, final adverse determination is reversed. BCBSM is required to authorize and cover the Petitioner's Pillar Procedure. BCBSM shall authorize the procedure within 60 days and provide the Commissioner with proof of the authorization within seven days after authorization is made

Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than sixty days from the date of this Order in the circuit court for the county where the covered person resides or the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of the Office of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.